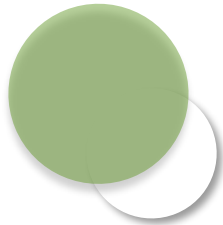




VAERS

Vaccine Adverse Event Reporting System



<http://vaers.hhs.gov>

VAERS

Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

[About VAERS](#) | [Report an Adverse Event](#) | [VAERS Data](#) | [Resources](#) | [Submit Follow-Up Information](#)

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. [Report an Adverse Event](#) using the VAERS online form or the new downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. [Reporte una reacción adversa](#) utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*

What is VAERS?

REPORT AN ADVERSE EVENT

Report significant adverse events after vaccination.

SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.

REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.

SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

National Childhood Vaccine Injury Act of 1986

Selected provisions

- **Vaccine Adverse Event Reporting System (VAERS)**
 - Accepts reports of adverse events following vaccination
- **Vaccine Information Statements (VIS)**
 - Required for childhood vaccines
- **National Vaccine Injury Compensation Program (NVICP)**
 - Compensates those injured by vaccines on a "no fault" basis



Vaccine Adverse Event Reporting System (VAERS)

- **National spontaneous (or passive) reporting system for adverse events after US-licensed vaccines**
 - Receives \approx 58,000 reports annually*
 - Accepts reports from healthcare providers, manufacturers and public
 - Signs/symptoms of AE are coded using the Medical Dictionary for Regulatory Activities (MedDRA)[±] terms and entered into a database
 - Primarily used for signal detection and hypothesis generation
- **Jointly administered by CDC and FDA since 1990**

* 2014-2018

± <http://www.meddra.org/>

Objectives of VAERS



- **Signal detection/hypothesis generation**
 - Detect new, unusual, or rare vaccine adverse events (AEs)
 - Identify potential risk factors in vaccine recipients for particular types of AEs
 - Monitor trends in known AEs, particularly increased reporting over time
 - Assess the safety of newly licensed vaccines
- **Rapidly respond to vaccine safety concerns or public health emergencies**
 - **Example:** large scale pandemic influenza vaccination program

What to report to VAERS

- Any medically important health event/adverse event following vaccination (events of concern to provider, patient or family) following immunization even if you are not sure the vaccine caused the event
 - Local: redness, swelling, pain at injection site
 - Systemic: fever, myalgia, headache
 - Allergic: hives, pruritis, anaphylaxis
 - Vaccination errors (e.g., wrong drug administered)
- The National Childhood Vaccine Injury Act mandates healthcare providers report specific AEs following vaccination and those contraindicated to receiving another dose of the vaccine
 - VAERS Table of Reportable Events
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf



VAERS Table of Reportable Events following vaccination

[https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS%20Table%20of%20Reportable%20Events%20Following%20Vaccination.pdf)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval** from vaccination
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination; MMR, MMRV, MM	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination; MMR, MMRV	<ul style="list-style-type: none"> A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

How to Report to VAERS: Two Options

1. Report online on the VAERS website (vaers.hhs.gov)
2. Report using a writeable pdf
 - Download the 1 page form
 - Complete and upload into the VAERS website

Two Ways to Submit an Online Report to VAERS



Option 1 - Report Online to VAERS (Preferred)

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.



Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

Checklist

What will I need to fill out the report?

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact

Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS accepts all reports from all reporters without making judgments on causality or judging clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

Example of A Signal Found in VAERS

- **Febrile seizures following inactivated influenza vaccine**
 - 2010-2011 influenza season: VAERS detected a febrile seizure signal
 - Signal was further assessed and quantified in other CDC safety systems*
 - Co-administration of inactivated influenza vaccine and pneumococcal conjugate vaccine to young children slightly increased the risk of fever and febrile seizures
- **Findings from CDC's ISO were incorporated into the Vaccine Information Statements (VIS)**

4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13), and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's www.cdc.gov/flu


Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine

8/15/2019 | 42 U.S.C. § 300aa-26




Another Example of A Signal Found in VAERS






- Administration of expired flu vaccine

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

[A-Z Index](#)

Search 

Morbidity and Mortality Weekly Report (MMWR)

CDC     

Notes from the Field: Administration of Expired Injectable Influenza Vaccines Reported to the Vaccine Adverse Event Reporting System — United States, July 2018–March 2019

Weekly / June 14, 2019 / 68(23):529–530


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[View suggested citation](#)

Influenza vaccination is recommended annually for persons aged ≥6 months for the prevention and control of influenza (1). Every year, injectable inactivated influenza vaccine (IIV) has a standard expiration date of June 30 for the upcoming influenza season (i.e., July 1–June 30 of the following year). Vaccination with an expired influenza vaccine might not protect against influenza infection because different influenza virus strains can be included in the vaccine each year; in addition, protection against viruses included in the vaccine could wane if vaccine potency decreases over time. During July 11, 2018–March 29, 2019 in the United States, the Vaccine Adverse Event Reporting System (VAERS) received 125 reports of 192 patients receiving expired IIV during the 2018–19 influenza season (2), during which time 169.1 million doses of seasonal influenza vaccine were distributed (3). Dates of vaccination were documented for 102 patients and ranged from July 2, 2018, to January 16, 2019. The number of expired vaccine doses administered increased in September and decreased after October, coinciding with dates when influenza vaccine is typically given (Figure). Ages were available for 103 vaccine recipients. Seventy-three recipients (70.1%) were identified as being in high-risk age groups for influenza; eight were aged <5 years, and 65 were aged >50 years (1). An additional six reports specified that the patient had been pregnant at time of vaccination; pregnancy outcomes were not

Article Metrics

Altmetric:



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Do your part for Vaccine Safety: Report to VAERS at vaers.hhs.gov



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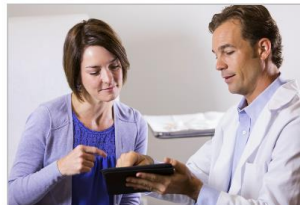
/ [en Español](#)

Report an Adverse Event

Online reporting is strongly encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. [Guidance on reporting vaccination errors](#) is available if you have additional questions.

Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.



Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

